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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/204,427	12/03/98	HADDADA	H 8076.102USC1

023552
MERCHANT & GOULD
P O BOX 2903
MINNEAPOLIS MN 55402-0903

HM22/0103

EXAMINER	
WILSON,M	
ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 01/03/01

Please find below and/or attached an Office communication concerning this application or proc eding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/204,427	HADDADA ET AL.	
	Examin r	Art Unit	
	Michael Wilson	1633	

-- The MAILING DATE of this communication app ars on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-8 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/150,011* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael C. Wilson.

Applicant's arguments filed 10-10-00, paper number 10, have been fully considered but they are not persuasive. Claims 1 and 3-5 have been canceled. Claim 14 has been added. Claims 6-8 and 14 are pending and under consideration in the instant invention.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/150011, filed on 1-3-94.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 6-8 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 6 and 14 recite the new limitations of "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1" which are considered new matter. The specification lists the promoter of the rep gene of parvovirus HI (page 14, line 15) but does not teach that a plurality of promoters of the rep gene of parvovirus HI were available. The specification as originally filed does not provide adequate support for a plurality promoters of rep gene of parvovirus HI. Therefore, the phrases are considered new matter.

The limitation of "the E1A and E1B transactivator sequences needed for its replication" lacks support in the specification as filed and is considered new matter. While E1A and E1B transactivator sequences are disclosed in the specification and deleted as claimed, the specification does not disclose sequences of the E1A and E1B that are needed for replication. The specification discloses "sequences needed for its replication" (page 2, line 13); however, the sequences are not E1A or E1B. If support for such a limitation is in the specification, applicants should point to such support by page and line number. Deletion of the phrase "needed for replication" is suggested to overcome this rejection.

2. Claims 6-8 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 6 and 14 recite the new limitations of "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1". The specification lists the promoter of the rep gene of parvovirus HI (page 14, line 15) but does not teach the sequence of any rep gene promoter of H1. The art at the time of filing Lebovitz taught two promoters of parvovirus H1 (Lebovitz et al., May 1986, J. Virol., Vol. 58, pages 271-80; page 272, col. 2, 3rd full paragraph "promoter at map position 4"; page 273, col. 2, "internal promoter at map position 40"). However, neither promoter of Lebovitz is a promoter of the rep gene of parvovirus H1 as claimed. If so, it cannot be determined whether the promoter at position 4 or 40 is the promoter claimed. In addition, Gu taught the p38 promoter of parvovirus HI with various mutations (Gu et al., 1992, Virology, Vol. 187, pages 10-17; page 10, col. 2). However, none of the promoters of Gu are a promoter of the rep gene of parvovirus of HI as claimed. If so, it cannot be determined which promoter applicants consider the rep gene promoter of parvovirus HI disclosed in the specification. Given the teachings in the specification taken with the art at the time of filing, the specification does not provide any written description of a promoter of the rep gene of parvovirus HI. Based on recent court decisions, "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1" lack a written description in the specification as the structure and function of such promoters have not been provided nor can the structure or function of these other promoters be envisioned by the description in the specification (*University of California v. Eli Lily & Co.* CAFC, July 22, 1997; *Fiddes v. Baird* Brd. Pat. App. Int. 30

USPQ2d 1481 1993; *Fiers v. Revel* 25 USPQ2d 1601 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* LTD (CAFC) 18 USPQ2d 1016 1991).

The limitation of "the E1A and E1B transactivator sequences needed for its replication" lacks written description (claim 14). While deletions of the E1A and E1B regions are disclosed in the specification, the specification does not provide written description for any and all E1A and E1B sequences that are needed for replication. Therefore, the limitation lacks written description in the specification because the structure of other E1A and E1B sequences needed for replication have not been provided nor can the structure of other E1A and E1B sequences needed for replication be envisioned by the description in the specification.

The limitation of "sequences needed for said adenovirus to enter cells in which said adenovirus infects" lacks written description (claim 14). The specification does not provide any description of sequences that are needed for the adenovirus to enter a cell. Therefore, the limitation lacks written description in the specification because the structure of sequences needed for an adenovirus to enter cells have not been provided nor can the structure of other sequences be envisioned by the description in the specification.

3. Claims 6-8 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 6 and 14 recite the new limitations of "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1". The specification lists the promoter of the rep gene of parvovirus HI (page 14, line 15) but does not teach the sequence of any rep gene promoter of H1. The art at the time of filing taught two promoters of parvovirus H1 at map position 4 and map position 40 (Lebovitz et al., May 1986, J. Virol., Vol. 58, pages 271-80; page 272, col. 2, 3rd full paragraph "promoter at map position 4"; page 273, col. 2, "internal promoter at map position 40"). However, neither promoter of Lebovitz is a promoter of the rep gene of parvovirus H1 as claimed. If so, it cannot be determined whether the promoter at position 4 or 40 as taught by Lebovitz is the promoter of the rep gene of parvovirus H1 disclosed in the specification. In addition, Gu taught the p38 promoter of parvovirus HI with various mutations (Gu et al., 1992, Virology, Vol. 187, pages 10-17; page 10, col. 2). However, none of the promoters of Gu are a promoter of the rep gene of parvovirus of HI as claimed. If so, it cannot be determined which promoter applicants consider the rep gene promoter of parvovirus HI disclosed in the specification. The specification does not provide an assay for one of skill to determine the promoter of the rep gene of parvovirus H1. Given the teachings in the specification taken with the art at the time of filing, it would have required one of skill undue experimentation to make the vector claimed with "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1".

In addition, for the vector claimed to be enabled, the nucleic acid sequence encoding a cytokine should be operatively linked to the promoter of the rep gene of parvovirus H1. If claim

6 is intended to claim a vector comprising multiple nucleic acid sequences encoding cytokines each of which are under the control of the promoter of the rep gene of parvovirus H1, the following claim language is suggested: an adenoviral vector comprising nucleic acids sequences encoding cytokines, each of which is operatively linked to the promoter of the rep gene of parvovirus H1.

Finally, the limitations of "the E1A and E1B transactivator sequences needed for its replication" and "sequences needed for said adenovirus to enter cells in which said adenovirus infects" lack enablement. While deletions of the E1A and E1B regions are disclosed in the specification, the specification does not provide adequate guidance for one of skill to determine any and all E1A and E1B sequences that are needed for replication. Nor does the specification provide adequate guidance for the sequences that are needed for the adenovirus to enter a cell. Therefore, the limitations lack enablement because the structure of other E1A and E1B sequences needed for replication and for an adenovirus to enter cells have not been adequately described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because it is unclear how the "nucleic acid sequences coding for several cytokines" differs from the "separate nucleic acid sequences coding for different cytokines". It cannot be determined how the two categories are related or differ. In addition, it is unclear whether the phrase "said nucleic acid sequences" refers to the "nucleic acid sequence coding for several cytokines" or the "separate nucleic acid sequences coding for different cytokines". Finally, it cannot be determined whether "separate promoters of the rep gene of parvovirus H1" are different promoters and whether each gene encoding a cytokine is operatively linked to one of the "separate promoters". Therefore, the structure and relationship of the various nucleic acid sequences and promoters cannot be envisioned and the metes and bounds of the claim cannot be determined.

Claims 6 and 14 are indefinite because it is unclear what applicants consider "promoters of the rep gene of parvovirus H1" and "a promoter of the rep gene of parvovirus H1". The specification does not teach the structure or function of such promoters and the art does not teach such promoters. Therefore, the metes and bounds of the promoters encompassed by the claims cannot be determined.

Claims 6-8 and 14 appear to be free of the prior art of record because the prior art of record does not teach or suggest an adenoviral vector comprising a nucleic acid encoding a cytokine or several cytokines under the control of a promoter of the rep gene of parvovirus HI as claimed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

Deborah Clark

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600